MOTION FILED
OCT 6 - 2006

(5)

No. 06-372

IN THE

SUPREME COURT OF THE UNITED STATES

FERRING B.V. AND AVENTIS PHARMACEUTICALS, INC.

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Pursuant to this Court's Rule 37.2(b), the Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully request leave of this Court to file the attached brief as *amicus curiae* supporting Petitioners. Respondent has withheld consent to the filing of this brief, thus necessitating the filing of this motion.[1]

PhRMA is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members invested an estimated $39.4 billion in 2005 alone toward the discovery and development of new medicines. They are responsible for most of the innovative medicines that have been approved for use in the United States over the past several decades.

Intellectual property principles are of critical importance to PhRMA's members. PhRMA is

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[1] Pursuant to this Court's Rule 37.6, PhRMA states that no counsel for a party authored this motion or brief in whole or in part, and no person, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/about_phrma/member_company_list/members/. Petitioner Aventis Pharmaceuticals, Inc. is an affiliate of sanofi-aventis U.S., which is a member PhRMA. Sanofi-aventis U.S. took no part in the preparation or submission of this brief.

interested in ensuring that patent law is applied in a way that promotes the timely development of new medicines, and strong and clear patent rights are essential for further innovation in drug development. The Federal Circuit's uncertain and broadly applied doctrine of inequitable conduct renders patents unenforceable even where the patentee engaged in no activity that violates the duty of candor and good faith before the United States Patent and Trademark Office ("PTO"). This creates an uncertain environment for PhRMA's members undertaking such innovation.

Based on the foregoing, amicus hereby moves to file this brief *amicus curiae* in support of petitioners in this case.

Respectfully submitted,

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Dated: October 6, 2006

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTEREST OF THE *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 3

ARGUMENT 4

CONCLUSION 16

TABLE OF AUTHORITIES

Page

CASES

A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392 (Fed. Cir. 1986) 7

Abbott Laboratories v. Torpharm, Inc., 300 F.3d 1367 (Fed. Cir. 2002) 6

Bowen v. Georgetown University Hospitals, 488 U.S. 204 (1988) 10

Burlington Industries, Inc. v. Dayco Corp., 849 F.2d 1418 (Fed. Cir. 1988) 6

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 12

Digital Control Inc. v. Charles Machine Works, 437 F.3d 1309 (Fed. Cir. 2006) ..... *passim*

FCC v. Pottsville Broadcasting Co., 309 U.S. 134 (1940) 13

FCC v. Schreiber, 381 U.S. 279 (1965) 13

Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003) 7

Hunt v. Cromartie, 526 U.S. 541 (1999) 15

Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (*en banc*) 2

Landgraf v. USI Film Products, 511 U.S. 244 (1994) 10

Molins PLC v. Textron, Inc., 48 F.3d 1172 (Fed. Cir. 1995) 9

Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376 (Fed. Cir. 1983) 6

Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464 (1962) 7

Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945) 14

Purdue Pharma L.P. v. Endo Pharms. Inc., 410 F.3d 590 (Fed. Cir. 2005) 3

Ruiz v. A.B. Chance Co., 234 F.3d 654 (Fed. Cir. 2000) 2

Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519 (1978) 12, 13

Walker Process Equipment Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965) 2, 9, 14

STATUTES AND REGULATORY MATERIALS

21 U.S.C. § 355 2

35 U.S.C. § 2 ..... 11, 12, 13

35 U.S.C. § 285 2

37 C.F.R. § 1.56 (2006) ..... *passim*

Duty of Disclosure, 57 Fed. Reg. 2021 (Jan. 17, 1992) 14

MISCELLANEOUS

Local Briefing: OxyContin Maker Victorious in Court, Hartford Courant, Feb. 2, 2006 3

Manual of Patent Examining Procedure § 609 (8th ed., rev. 5 2006) 8

Stephen A. Merrill, et al., National Research Council, A Patent System for the 21st Century, 121-23 (2004), http://www.nap.edu/html/patentsystem/0309089107.pdf 1

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits this brief as *amicus curiae* supporting Petitioners.

INTEREST OF THE *AMICUS CURIAE*

Inequitable conduct is now the defense of last resort in patent cases. As in this case, these assertions are typically founded on the accused infringer's second-guessing of a patent applicant's disclosures to the PTO. Because it is practically impossible for patent applicants to submit all potentially relevant information to the PTO, and because adversaries can always later contend that even innocent statements are nonetheless incomplete or misleading, infringers now routinely resort to charges of inequitable conduct in any attempt to avoid liability. Such allegations are especially pernicious when an infringer's "specific intent" contentions are based only on inference and circumstance. Indeed, because this defense turns entirely on a later assessment of the applicant's subjective intent, a recent study by the National Academies of Science has recommended abolition of the defense in its entirety. *See* Stephen A. Merrill, et al., National Research Council, A Patent System for the 21st Century, 121-23 (2004), http://www.nap.edu/html/patentsystem/0309089107.pdf.

Pharmaceutical companies inordinately suffer the consequences that flow from the Federal Circuit's present inequitable conduct doctrine, not because their conduct in procuring patents differs from other patent applicants, but because the Hatch-Waxman

Act offers the bounty of 180-day exclusivity to any would-be generic manufacturer who succeeds in challenging the enforceability of an innovator's drug patent.[2] 21 U.S.C. § 355(j) (2006). A finding of inequitable conduct has grave consequences for patentees because it renders the entire patent unenforceable. *See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (*en banc*). Moreover, accused infringers that win a judgment that a patent is unenforceable have recovered their reasonable attorney fees. *See, e.g., Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 669-70 Cir. 2000) (citation omitted) ("A finding of inequitable conduct can be the basis for awarding attorney fees under [35 U.S.C. § 285].").

Such a judgment also often leads to follow-on antitrust litigation pursuant to *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 174 (1965), in which the accused infringer alleges that the patentee improperly enforced its patent knowing that it was procured by fraud on the PTO in violation of section 2 of the Sherman Act. In such cases, the accused infringer could also win treble damages from the patentee.

Nor are the consequences of inequitable conduct limited to litigation. In one recent example, a

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[2] Approximately forty percent of the patent cases decided in the last three years by the Federal Circuit that address inequitable conduct issues involved pharmaceutical patents.

PhRMA member laid off more than half of its employees after the district court ruled that its patent was unenforceable due to inequitable conduct before the PTO and the Federal Circuit at first affirmed the district court. *See Local Briefing: OxyContin Maker Victorious in Court*, Hartford Courant, Feb. 2, 2006, at E2 (reporting that Purdue Pharma L.P. had "cut its workforce of 3,300 by 1,863" after the district court's ruling); *see also Purdue Pharma v. Endo Pharm.*, 410 F.3d 690 (Fed. Cir. 2005) (affirming the district court), *vacated on panel rehearing*, 438 F.3d 1123 (2006). On rehearing, the same panel of the Federal Circuit ultimately vacated the district court's holding of inequitable conduct, *see id.*, but by then, enormous damage had been done. That the same panel of the Federal Circuit could unanimously reach opposing results in the same case within a few months demonstrates the uncertainty that make this area of the law so destructive.

SUMMARY OF ARGUMENT

Despite the serious consequences that flow from a finding of inequitable conduct, the Federal Circuit and district courts have not adopted any reliable standard for information that a patent applicant must submit to the PTO during prosecution, that is, what information is "material." In fact, the Federal Circuit has set forth no less than five different standards for what is material, effectively nullifying the PTO's definition of what is "material" embodied in its regulations. Consequently, a patent applicant which fully complies with the PTO's requirements can still

be found to have committed inequitable conduct by a court in subsequent litigation.

By ignoring the PTO's definition of material information, the Federal Circuit has misunderstood this Court's decisions regarding an agency's role in defining the rules and procedures that apply in proceedings before it.

By lowering the threshold for a finding of deceptive intent from evidence of specific intent to mere negligence, the Federal Circuit's standard could open all errors of judgment during the prosecution of a patent to charges of inequitable conduct. This approach gives incentive to an infringer to scour the patent file wrapper for any omission that might be through an advocate's hindsight reconstruction of events, be cast as a misrepresentation. The Federal Circuit's approach breeds uncertainty and leads to wasteful litigation in both patent cases and follow-on antitrust cases. The present case typifies this problem.

ARGUMENT

I. The Federal Circuit's Inequitable Conduct Doctrine Has Expanded Beyond its Purpose and Led To Uncertainty And Wasteful Litigation

Courts grappling with the two elements of inequitable conduct ("materiality" and "intent to deceive") have created a patchwork of cases that create uncertainty and substantial burdens for both patent applicants (PhRMA members in particular) and the PTO. Although Congress established the

Federal Circuit to bring consistency to the patent law, that court has presided over an unprecedented growth in the number of cases where charges of inequitable conduct are made, due in large part to the lack of a clear legal standard.

Today, as the petition correctly points out, there are five different legal standards for materiality applied by courts. These include current PTO Rule 56, 37 C.F.R. § 1.56 (2006), its predecessor rule, and three judicially-created standards: the objective "but for" test; the subjective "but for" test; and the "but it may have been" test. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-15 (Fed. Cir. 2006) (describing five tests for materiality). Notwithstanding a materiality standard promulgated by the administering agency, a patent applicant seeking to comply with its duty of candor is left without clear guidance as to what information should be disclosed to that agency.

The Federal Circuit's approach requires patent applicants to consider each of these standards of materiality in determining what, if any, information should be submitted to the PTO in order to avoid allegations of inequitable conduct in future litigation. *See id.* at 1316. Furthermore, the Federal Circuit's approach is fundamentally unfair because it creates the prospect that an applicant could fully comply with the current law of materiality and still have its patent held unenforceable based on a different standard for materiality applied by the court years down the road.

The patent applicant's burden is further compounded by the Federal Circuit's current sliding scale of deceptive intent. *See, e.g., Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) (citation omitted) ("[T]he intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission."). At its extreme, as in this case, this elastic intent analysis permits a court to render a patent unenforceable based upon *mere negligence*, a "should have known" standard.

The Federal Circuit initially required evidence of intentional misconduct. *See Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983). But the court has since adopted a sliding scale approach where the greater the materiality, the lower the showing of intent must be such that—as in this case—omissions that are found highly material only require evidence of what amounts to mere negligence to obtain summary judgment. Indeed, the Federal Circuit acknowledged that allegations of inequitable conduct had become so commonplace as to be a "plague" and attempted to clarify the proof required for intent in an effort to address its concern. *See Burlington Indus. Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). This clarification, however, did not last for long. *See Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).

It is one thing for a fact finder to draw a permissive inference that an applicant acted with intent to deceive based upon a highly material nature

of the statement or omission. It is quite another for a court to conclude as a matter of law, based only on a record submitted in connection with a motion for summary judgment, that an applicant acted with fraudulent intent by not including facts which only now the Federal Circuit has identified to be material. *See Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962) (cautioning against a grant of summary judgment where motive and intent play leading roles).

Even subjective good faith may offer little protection to a charge of inequitable conduct, as the court may find deceptive intent based on its retrospective assessment of what the patent applicant should have known about the materiality of an undisclosed reference. *See A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1398 (Fed. Cir. 1986) ("[A]determination of inequitable conduct will not be avoided if knowledge of materiality or gross negligence greatly outweighs the lack of deceptive intent."). But the doctrine of inequitable conduct is intended to guard against dishonesty in the prosecution of a patent, not errors in judgment.

The uncertainty regarding which materiality standard a court might apply in future litigation, coupled with the "should have known" standard of intent, imposes significant burdens on patentees, requiring them to evaluate every potentially relevant piece of information known to them under a medley of different materiality standards that might ultimately apply. This burden is particularly heavy for PhRMA members because, due to the FDA approval process,

they often engage in further research related to a product after a patent application has been filed, generating significant quantities of additional information that may or may not be material under one of the Federal Circuit's materiality standards.

Moreover, PhRMA members may be aware of vast bodies of literature that may be material under at least one of the Federal Circuit's materiality standards. To avoid a potential finding of inequitable conduct, the applicants may need to review all such information under each of the Federal Circuit's standards and submit to the PTO all of the information that is even arguably material under any of those standards. Thus, the Federal Circuit's approach burdens both patent applicants and the PTO itself, which must review the information submitted by applicants. *See Manual of Patent Examining Procedure* § 609, at 600-141 (8th ed., rev. 5 2006) ("An information disclosure statement filed in accordance with the provisions of 37 C.F.R. 1.97 and 37 C.F.R. 1.98 will be considered by the examiner assigned to the application.").

Nor does full disclosure of all arguably relevant material to the PTO shield patent applicants from allegations of inequitable conduct under the Federal Circuit's approach. Even if an applicant discloses all potentially relevant information under each of the Federal Circuit's materiality standards, the applicant may still face allegations that it committed inequitable conduct by "burying a particularly material reference in a prior art statement containing

a multiplicity of other references." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

The potential harm to a patent applicant does not end with a judgment that its patent is unenforceable. Armed with such a judgment, accused infringers often bring follow-on antitrust litigation pursuant to *Walker Process*, 382 U.S. at 174. Such litigation further burdens the courts, and it subjects patent owners to the risk of claims for huge treble damages in follow-on antitrust cases, all predicated on a doctrine that is rife with uncertainty. The current state of affairs cries out for intervention by this Court.

II. The Federal Circuit Has Improperly Ignored the PTO's Standard for Materiality

The petition notes that the Federal Circuit has consistently held, in determining whether information is material for its inequitable conduct inquiry, that it need not follow the PTO's rule that defines materiality, 37 C.F.R. § 1.56(b) (2006). *See, e.g.*, *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006). Indeed, the Federal Circuit has expressly held that neither the PTO's pre-1992 regulation nor the PTO's present regulation "supplant[s] or replace[s]" the Federal Circuit's case law.[3] *Id.* at 1316. Instead, the Federal Circuit has

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[3] Respondent argues that the present rule, which was published in the Federal Register on January 17, 1992, does not apply here because the patent issued on September 10, 1991. This argument might have merit if the PTO's rule prescribed law (continued...)

viewed those regulations as "additional test[s] of materiality" beyond the three judicial standards for materiality that the Federal Circuit applies. *Id.*

The PTO's Rule defines the materiality of information provided or withheld by an applicant as information that is not cumulative to other information of record in the application that

> (1) . . . establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
>
> (2) . . . refutes or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

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limiting a regulated entity. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988). However, this Court has limited "retroactive" measures to those that "impair[] rights a party possessed when he acted, increase[] a party's liability for past conduct, or impose[] new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The PTO's 1992 rule has no such consequences.

37 C.F.R. § 1.56(b) (2006).[4] No one contends that the information at issue in this case is material under this standard.

By adhering to its own constantly expanding view of materiality to establish inequitable conduct, the Federal Circuit has ignored the function granted to the PTO by Congress, while at the same time ignoring—as properly pointed out in the petition—established principles of administrative law.[5]

In prescribing the "powers and duties" of the PTO, Congress provided that the Office

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[4] The Rule further defines a "*prima facie* case of unpatentability" as "established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden of proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." 37 C.F.R. § 1.56(b) (2006).

[5] There is no challenge to the validity of the PTO's regulation in this case. The PTO has taken the position that Rule 56 is grounded in 35 U.S.C. § 2(b)(2) (or its predecessor 35 U.S.C. § 6(a)). *See, e.g.*, Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992). And no one is challenging that assertion. If, on the other hand, a PTO regulation were inconsistent with or based on an impermissible construction of a statute, it would be entitled to no deference. *See, e.g., Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

> may establish regulations, not inconsistent with law, which –
>
> (A) shall govern the conduct of proceedings in the [PTO];
>
> (B) shall be made in accordance with section 553 of title 5;
>
> (C) shall facilitate and expedite the processing of patent applications . . . ; [and]
>
> (D) may govern recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . .

35 U.S.C. § 2(b)(2) (2000).

Relying on this statutory authorization and command, the PTO has over the years defined the "Duty to disclose information material to patentability." 37 C.F.R. § 1.56 (2006). By its disavowal of the PTO's regulation, the Federal Circuit has acted in a manner that is inconsistent with this Court's landmark administrative law decisions that set the boundaries between federal agency and federal court authority. *See Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519. 543-44 (1978):

> Absent Constitutional constraints or extremely compelling circumstances, the "administrative agencies 'should be free to fashion their own rules of procedure and to pursue methods of inquiry

> capable of permitting them to discharge their multitudinous duties.'" *FCC v. Schreiber*, 381 U.S. [279,] 290 [1965].

435 U.S. at 543-44, quoting *FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 143 (1940).

The principles of *Vermont Yankee* apply *a fortiori* here because Congress made it clear that the PTO regulations "shall govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A).[6]

This Court's decision in *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), does not support the Federal Circuit's posture on inequitable conduct.

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[6] There are practical reasons that support following the PTO's disclosure rule. In responding to the numerous written comments made on the proposed rule, some of which contended that it should not be adopted because the existing rule was "presently in conformance to the materiality standard being applied by . . . the Federal Circuit," the PTO stated that

> the amendment to § 1.56 was proposed to address criticism concerning a perceived lack of certainty in the materiality standard. The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the Office with the information necessary for effective and efficient examination of patent applications.

57 Fed. Reg. at 2023. The PTO is in a position to decide what information is or is not material.

In that case, the "fraud" was not limited to the PTO and its processes, but included fraudulent behavior in federal courts. It is one thing for a federal court to apply equitable principles to protect the integrity of the judicial process. It is a far different thing for a federal court to review a person's conduct before an agency based upon a different set of standards than the agency itself applies.

Despite the PTO's clear rule, the Federal Circuit has continued to breed uncertainty and prolonged litigation, not only in patent infringement actions, but also in antitrust suits that spring from findings of inequitable conduct. Although the PTO has defined "what information the Office considers material to patentability," 57 Fed. Reg. at 2024, in 37 C.F.R. § 1.56 (2006), the Federal Circuit continues to apply different standards which are, of course, unknowable by the patent applicant at the time he engages in the allegedly improper conduct. *See Digital Control Inc.*, 437 F.3d at 1314-15.

III. The Federal Circuit's Affirmation of Summary Judgment On the Intent Issue Is Emblematic.

This case is the best example of the pitfalls of the present state of the Federal Circuit's doctrine of inequitable conduct. The essence of the judgment of inequitable conduct in this case, as affirmed by the Federal Circuit, is that the applicant did not disclose that certain non-inventor declarants had *prior* relationships with the applicant and that the applicant *should have known* this information was highly material.

Here, the patent applicant submitted declarations, the truthfulness of which are unchallenged, from distinguished experts with impeccable credentials. Based solely upon evidence of an inadvertent omission of past unrelated professional connections -- which may only bear on the relative weight to be given the declarations -- the Federal Circuit found there to be no dispute that the applicant intended to deceive the PTO. In so doing on summary judgment, the Federal Circuit plainly failed to resolve all factual disputes and all inferences in the non-movants favor. *See Hunt v. Cromartie,* 526 U.S. 541, 552 (1999) (district court erred because "it either credited appellees' asserted inferences over those advanced by appellants or did not give appellants the inference they were due.").

Moreover, the Federal Circuit has adopted what amounts to a *per se* rule governing the submission of non-inventor declarations to the PTO. But this new judicial rule brings only greater burden to the patent applicant, and greater uncertainty to the patent system. Patent applicants have little or no control over third parties whose opinions may be sought to aid the PTO in its determinations, and may have difficulty convincing outside experts to subject themselves to personal questioning *even when each and every factual statement in their declarations are indisputable true.* When, as here, patents are struck down even though all of the information submitted to the PTO on the merits of the issue was entirely truthful, the intended incentive of the patent system to reward invention is subverted by a desire to

presume the worst of those seeking otherwise entirely legitimate patent protection. By so doing, the Federal Circuit has only further burdened the PTO and patent applicants and increased the opportunity for mischief.

CONCLUSION

The petition has clearly demonstrated the lack of certainty created by the Federal Circuit's ever-expanding approach to inequitable conduct. This Court's grant of the petition and ultimate clarification of the standards for materiality and intent will return the doctrine to its proper roots.

Respectfully submitted,

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